

Application Number: 10/798,594

Reply To Office Action of NOVEMBER 8, 2005

Remarks

Claims 1-27 were pending in this application. Claims 1, 14 and 16 have been amended. Applicant has amended the Specification to clarify discrepancies spelling and wording, as per the Examiner's request. The amendments made herein to the Specification and claims do not incorporate new matter into the application as originally filed. Support for the amendments can be found in the drawings and throughout the instant Specification.

Clarification of Office Action Responsive Date

The Examiner has indicated that this Office action was in response to communications filed 02 November 2005. Applicant has no record of communications filed on that date. Applicant's records indicate the last communication in this case filed as of March 11, 2004, the filing date of the present application. Applicant respectfully requests clarification.

Filing of and IDS herewith

The Examiner has objected to the listing of references in the Specification as an improper information disclosure statement under 37 CFR §1.98(b), as this section requires a list of all patents, publications, or other information submitted for consideration by the Office be submitted in a separate paper. In response, Applicant respectfully submits this communication to make of record the document(s) cited in FORM PTO-1449. It is respectfully submitted that the disclosure of the above documents does not constitute an admission that they are relevant or material to the claims or are "prior art" to the subject application. The citation of the above documents should not to be considered as a representation that no better art exists or that a search has been made.

Changes to the Abstract and Specification (Correct Drawing Numbering)

The Examiner has objected to the Abstract because it is allegedly written in claim form. Applicant has made corrections to the Abstract pursuant to the Examiner's request. The Abstract has been edited to delete the legal phraseology and for clarity. The Examiner has objected to the Drawings as the drawing numbering did not match the Specification.

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Accordingly, Specification paragraphs 0011 and 0012 have been amended to match the drawing numbering of Figs. 1 and 2. Applicant submits these amendments correct the drawing numbering mismatch and corrected drawings are not required. Applicant respectfully requests that the Examiner withdraw the objections to the Abstract, Drawings and Specification.

Claim Objections

Claim 16 was objected to because it was identical to Claim 15. Applicant has amended Claim 16 to correct the duplication error. Applicant respectfully requests that the Examiner withdraw the objections to Claims 16.

Claim Rejections under 35 USC § 102

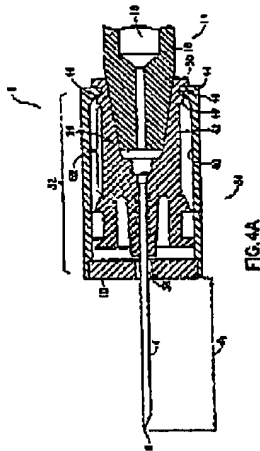
The Examiner has rejected Claims 1-27 under 35 U.S.C. §102(e) as being anticipated by Alchas et al., U.S. Published Application Number US 2002/0068909. (hereinafter "909"). Independent Claims 1 and 14, as presently amended, now recite the limitations of a specific extension of the needle beyond the limiter. This limitation which has been incorporated into Claims 1 and 14 are disclosed in the Specification e.g. Paragraph [00029].

As an initial matter, it should be noted that aspects of the present invention are directed to a device having a specialized limiter surrounding a needle having two distinct positions, both of which allow the needle to extend from the limiter. The limiter is moveable from a first position in which the needle extends a substantial distance from the limiter, so that the needle is insertable into a vial stopper and the lumen of the needle is able to fully penetrate the vial stopper so that medication may be aspirated through the needle into the syringe. The specialized limiter is then lockable into a second position in which the limiter is used to precisely set a distance that the needle extends beyond the skin engaging surface, and thus depth that the lumen of the needle is penetrated into the skin. Thus, first the needle extends beyond the limiter a distance d_1 allowing usage of the needle in a vial and then the needle extends beyond the limiter a distance d_2 allowing usage of the needle as an intradermal delivery device. This is best demonstrated by Applicant's Fig 4A and Fig. 4B, reproduced below for the convenience of the Examiner:

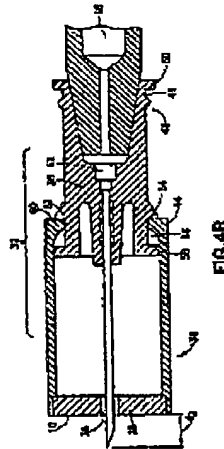
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Applicant's First Position



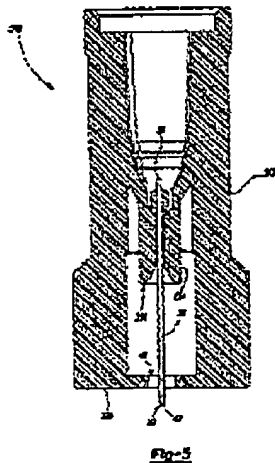
Second Position



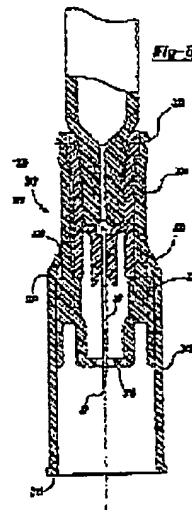
The Examiner contends the '909 reference shows the features as claimed as exemplified by a First Position in Figure 5 of '909, and a second position as shown in Figure 8. Figure 5 and Figure 8 of published application '909 are reproduced below for the convenience of the Examiner:

Published Application '909 Examiner Cited:

First Position



Second Position



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As can be seen from the '909 reference figures the first position and extension of the needle from the limiter in the '909 reference, as cited by the Examiner, would not allow access to a vial. Furthermore, the second position in the '909 reference, as cited by the Examiner, does not allow usage of the '909 device as an intradermal delivery device in that condition.

To support a rejection of a claim under 35 U.S.C. § 102, it must be shown that each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference. In addition, the prior art reference must disclose the limitations of the claimed invention "without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." Therefore, since '909 does not describe or suggest any of the first needle length limitations or vial access provisions, this reference cannot anticipate the Applicant's invention as claimed. Applicant respectfully requests that the Examiner withdraw the 35 U.S.C. §102 rejections against Claims 1-27.

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Conclusion

In view of the Remarks above, applicant respectfully submits that Claims 1-27 are in condition for allowance, and respectfully requests that the Examiner earnestly reconsider the rejections and objections of the present application. Applicant hereby authorizes the Commissioner to charge the fees necessary in connection with this Response, IDS, and Extension of Time and any other fees necessary in connection with this application, to Deposit Account Number 02-1666.

In light of the above amendments and remarks, Applicant respectfully requests that the Examiner enter the amendments and consider the remarks made herein. Consideration and prompt allowance of the claims are respectfully submitted.

Any questions concerning this application or amendment may be directed to the undersigned agent of applicant.

Respectfully submitted,

By: 

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